



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

SEP 23 1998

Ms. Linda M. Gearke
Manager, Family Care Product Division
Conklin Company, Inc.
551 Valley Park Drive
P.O. Box 155
Shakopee, Minnesota 55379

Dear Ms. Gearke:

This is in response to your letter of September 14, 1998 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that the Conklin Company, Inc. is making the following claim, among others, for the product "Arthritis & Joint Support."

"Arthritis & Joint Support"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product, and the inclusion of the term "arthritis" in the product name, suggests that the product is intended for use to treat, prevent, mitigate, or cure disease, namely arthritis. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

978-0163

LET 222

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement,
HFC-200

FDA, Minneapolis District Office, Office of Compliance, HFR-MW340

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (File)

HFS-450 (file, r/f, OSN#61308)

HFD-310 (BWilliams)

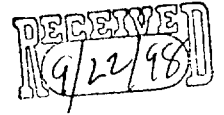
HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

f/t:HFS-456:rjm:9/23/98:docname:61308.adv:disc32



September 14, 1998

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
200 C St., SW
Washington, DC 20204

RE: Dietary Supplement Statement of Support Notification

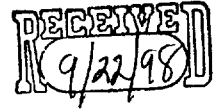
To Whom It May Concern:

The Conklin Company, Inc., 551 Valley Park Drive, Shakopee, MN 55379, who is the distributor of the following dietary supplement product, intends to make the following statement of support: "Promotes Healthy Joints and Cartilage." This claim is being made for the product, Arthritis & Joint Support. This submission is being made in compliance with 21 CFR 101.93.

The undersigned is an authorized representative of the Conklin Company, Inc. and certifies that the information contained in this notice is complete and accurate, and that Conklin Company, Inc. has substantiation that the above statement is truthful and not misleading.

Linda M. Gearke
Manager, Family Care Product Division

61308



September 14, 1998

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
200 C St., SW
Washington, DC 20204

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Linda M. Gearke
Manager, Family Care Product Division

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